May 13, 1969 A POSNER ET AL 3,443,421

DISPOSABLE TONOMETERS

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FIG. 1

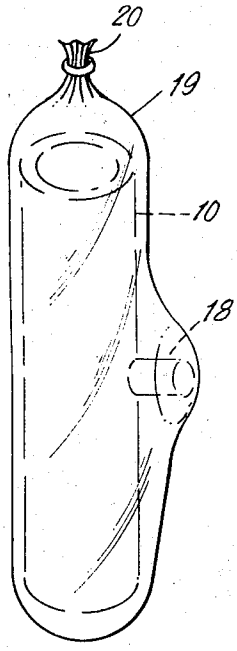


FIG. 2

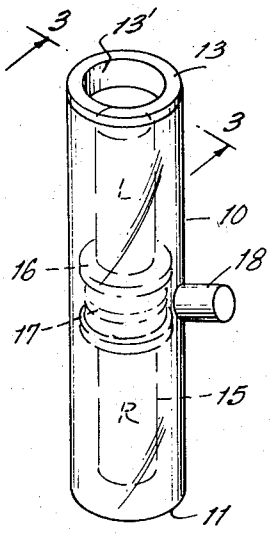
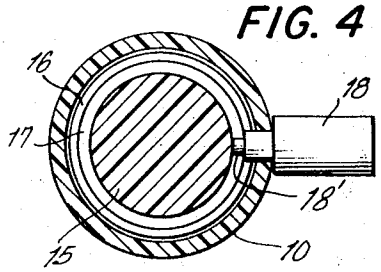


FIG. 4



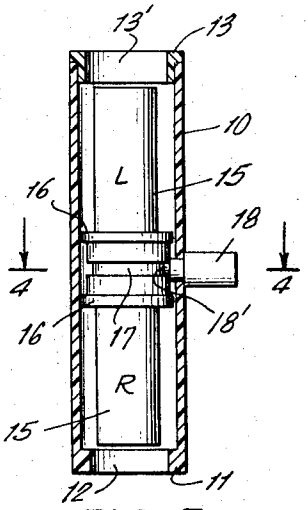
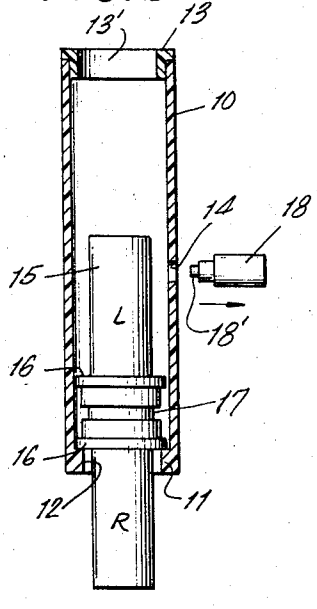


FIG. 3

FIG. 5



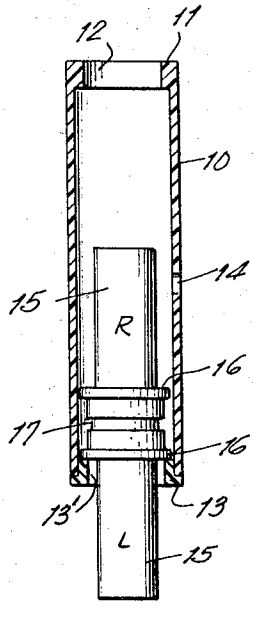


FIG. 6

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May 13, 1969 A POSNER ET AL 3,443,421

DISPOSABLE TONOMETERS

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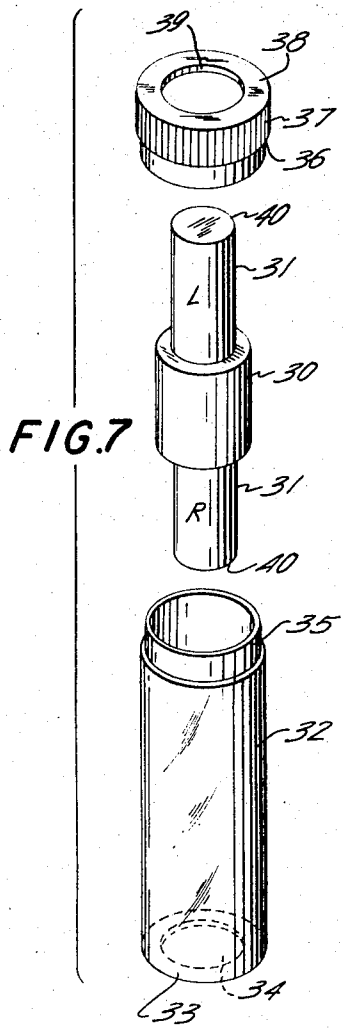

FIG.7

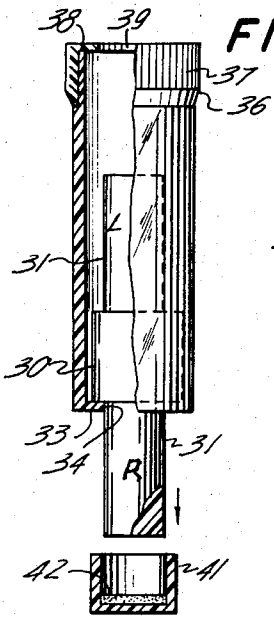

FIG.8

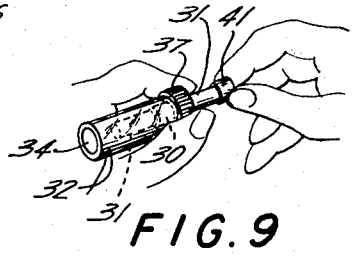

FIG.9

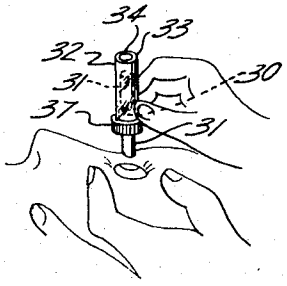

FIG.10

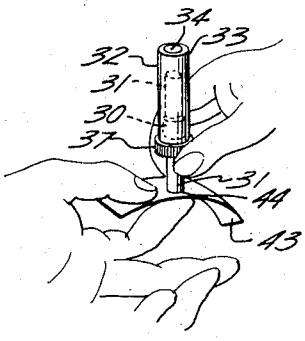

FIG.11

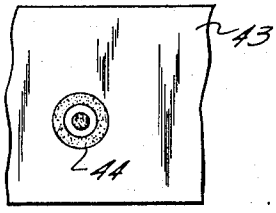

FIG.12

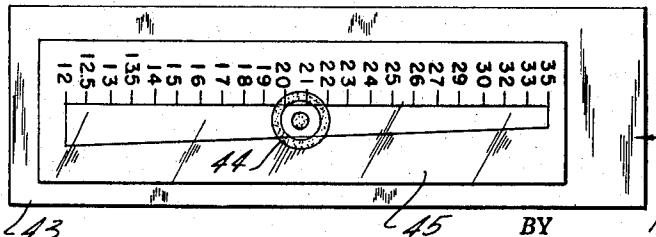

FIG. 13

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DISPOSABLE TONOMETERS

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Continuation-in-part of application Ser. No. 453,604, May 6, 1965. This application May 10, 1967, Ser. No. 655,255

Int. Cl. A61b 9/00

U.S. Cl. 73—80 11 Claims

ABSTRACT OF THE DISCLOSURE

A simple, inexpensive disposable tonometer is provided by means of which screening programs can be readily and effectively carried out on large groups of population segments for determining the existence of glaucoma or incipient glaucoma. The tonometer itself comprises a cylindrical rod which has a hub intermediate its ends and this tonometer is suitable for use in a hollow cylindrical container having at least one open end with closure means which will permit the insertion of the tonometer within the cylinder and yet prevent the tonometer after it has been inserted from exiting in its entirety from within the cylinder.

This application is a continuation-in-part of our copending applications Ser. No. 453,604, filed May 6, 1965 and Ser. No. 554,861, filed June 2, 1966, both now abandoned. An applanation tonometer according to the present invention is based on the principle of the Maklakov tonometer. It has not heretofore been possible however to provide an inexpensive disposable tonometer employing this principle which is capable of use by ophthalmologists as well as by non-ophthalmologists. The main object of the present invention is to make this possible for the first time. The new tonometer of the present invention also makes it possible to improve and facilitates procedures for testing human eyes for intra-ocular pressure and to determine early changes or abnormalities which can lead to glaucoma, which if unrecognized and untreated leads to loss of vision and blindness.

In the accompanying drawings, two embodiments of the invention are illustrated:

FIG. 1 is an elevational perspective view of one embodiment of the new tonometer with an outer membrane covering;

FIG. 2 is a view similar to FIG. 1 with the outer covering removed;

FIG. 3 is a sectional elevational view of the tonometer taken on line 3—3 of FIG. 2;

FIG. 4 is a transverse cross-sectional view on an enlarged scale taken on line 4—4 of FIG. 3;

FIGS. 5 and 6 are views similar to FIG. 3 but wherein the tonometer proper is in its position for use after removal of the fastening element;

FIG. 7 is an exploded view in perspective of the second embodiment of the tonometer and its container;

FIG. 8 is an elevational view partly in section of the modified tonometer and its container together with a staining cap;

FIG. 9 illustrates in perspective the assembled tonometer and container showing the staining cap in use;

FIG. 10 shows how the tonometer is used in measuring intra-ocular pressure of a human eye;

FIG. 11 shows how the impression on the end of the tonometer shaft is transferred to a paper strip to make a visible record;

FIG. 12 is a fragmentary view of the paper strip of FIG. 5 showing a typical impression thereon made by a stained end of the tonometer shaft; and

FIG. 13 is a plan view of the paper strip with its impression thereon beneath a transparent scale in order that the signals of the impression can be translated into terms of pressure.

Referring to the drawing, numeral **10** designates a combination container and handle which is preferably but not necessarily composed of a transparent plastic, such as methyl methacrylate. This member **10** is of hollow cylindrical shape and is provided at one end with an inturned flange **11** having a central aperture **12** for a purpose to be explained hereafter. At its other end, member **10** is provided with a snugly fitting pull-out ring **13** having a central aperture **13'** which is normally in the position shown until use of the tonometer has been completed. Ring **13** is preferably but not necessarily composed of an opaque epoxy resin and is usually colored yellow but other colors or no color at all may equally well be used. Intermediate the ends of member **10** is a side wall opening **14** for a purpose to be explained below.

The tonometer proper is composed of a rod **15** usually of the same epoxy resin as the ring **13** and midway between the ends of the rod **15** there is a stepped hub or central enlargement **16** provided with an external annular groove **17**. This annular groove **17** is normally in registration with wall opening **14** in member **10** until such time as it is desired to use the tonometer and in order to maintain the tonometer centered within and protected by member **10** a pin or the like **18** is provided which has a reduced end **18'** to maintain the desired substantially immobile relationship of the parts shown in FIG. 3. The hub **16** in effect divides the rod **15** into two equal halves and the entire rod with its hub weighs precisely 5 gms. However, it can also be made to weigh 7.5 gms. or 10 gms., as may be required for specific purposes. These exact weights are necessary in order to be able to interpret and correlate the results obtaind from use of the tonometer. At each end of the rod **15** a suitable stain is applied in a thin uniform layer and this stain is of a nature per se known and contains a hygroscopic material such as glycerine in order to prevent drying out. The entire tonometer and the parts so far described are packaged within a member or bag **19** which is preferably of a thin transparent plastic material with one end brought together in air-tight manner as shown at **20** in FIG. 1. The entire assembly is then subjected to sterilization in any suitable manner per se known and is ready to be stored until used or for shipment to the place of intended use where it can be stored until needed.

In using the tonometer, the member or the like **19** is removed and the person to use the tonometer then grasps it by member **10** and the pin or the like **18** is pulled out and removed, thus allowing the tonometer and its hub to move freely within member **10**. One position (FIG. 6) of the rod **15** is used to test the left eye of a patient as indicated by the letter L thereon and the other position (FIG. 5) of the rod is used to test the right eye of a patient as indicated by the letter R thereon. After removal of pin **18** the tonometer and hub are held in vertical position by member **10** and the entire tonometer and hub slides down, for example, until the hub **16** comes into contact with inturned flange **11** (FIG. 5). Then the stained end of the rod **15** is allowed to rest briefly on the eye to be tested and the 5 gm. weight causes a certain amount of applanation or flattening depending upon the state of health of the eye so that the intra-ocular pressure can be determined. The portion of the eye in contact with the end of the rod forms a pattern on the rod end. By inverting member **10** the tonometer and hub slide in the opposite direction and the other eye of the patient is similarly tested (FIG. 6). After pulling out the tonometer from member **10** and at the same time forcing out ring **13**, the pattern of the imprint on the rod end is then transferred to a suitable record such as a patient's card

or the like by bringing the rod end into contact with a moistened portion of the card to form an impression or reproduction of the pattern on the rod end. After both eyes have been tested the entire device is thrown away or discarded and a fresh pre-sterilized one used for each succeeding patient.

A tonometer in accordance with this embodiment has a number of advantages not obtainable from previously known tonometers. It is very simple and inexpensive and can be used both by ophthalmologists for office or hospital procedures or can be used by non-ophthalmologists in the field or at any desired location such as a village or town where it is desired to make a mass screening test of the inhabitants for glaucoma. No previously known tonometer has been capable of such use or application or of being used by unskilled or untrained personnel. The tonometer has the added advantage that it is pre-sterilized and is only used after the protective membrane or the like **19** has been removed and since it has not been used on any other patient there is no danger of transmitting any germs or any communicable diseases existing in the eyes of a preceding patient because it has been found that ordinary sterilizing procedures such as heat and/or alcohol are unsatisfactory for field work or for remote locations by untrained personnel. The feature of transferring the imprint to paper serves not only as a permanent record, but also is a check on the validity of the measurement and the proper technique in using the instrument. This is of special importance in any statistical study dealing with the incidence of glaucoma.

The invention is further characterized by the fact that member **10** is a combination handle and enclosure for the tonometer, thus greatly simplifying the construction and making it possible to achieve the desired results. At the same time, the new tonometer is of such precise manufacture that it can be used by ophthalmologists in the operating room, for example, preceding cataract or glaucoma surgery or during retinal detachment surgery and can also be used in clinic or office practices during an epidemic of contagious eye diseases. The new tonometer can also be used in the presence of an existing inflammation of the eyes and, in general, provides a simple, novel and extremely useful device, lending itself to mass testing or screening programs.

In actual shipment, the device as shown in FIG. 1, can be suitably packaged in a protective container (not shown) made of paper, thin cardboard or the like which is provided with instructions for use and illustrations of the manner of employing the device. When produced in even moderately large quantities, the present tonometer costs only a small fraction of the cost of standard tonometers and is so inexpensive that each tonometer can be thrown away after a single use. This is particularly important where the tonometer is to be used by non-ophthalmologists since the chance of infection or transmission of infection from one patient to another is eliminated.

Intra-ocular pressure is measured in the same manner as that described below with reference to the other embodiment. In the other embodiment shown in FIGS. 7 through 11, the tonometer proper is made up of a plain smooth surfaced cylindrical centrally disposed enlarged hub portion **30** with cylindrical plunger shafts **31** of lesser diameter projecting therefrom in axial alignment.

As will be observed, a cylindrical, preferably transparent container **32** made of glass or synthetic plastic is used to house the tonometer and at one end of the container **32** there is an annular flange **33** having a central opening **34** which is of such size that the tonometer shaft **31** passes readily therethrough in either direction but of such size that the enlarged centrally disposed hub **30** cannot pass therethrough. In this way the annular flange **33** acts as a limit or stop for movement of the tonometer while still exposing one end of the shaft **31** as will be clear for example from FIG. 8. The opposite end of container **32** is provided with a vertical annular flange portion **35** of slightly reduced diameter as compared with the main body of the container and this portion **35** is adapted to receive a snugly fitting cap member **36** having a milled or roughened portion **37** for ease of manipulation. Cap **36** is provided at its outermost end with a lateral inwardly extending annular ring or flange **38** leaving a central opening **39** through which the other shaft of the tonometer can pass freely but of such size, like opening **34**, that the enlarged centrally disposed hub **30** cannot pass therethrough so that flange **38** serves as a limit or stop for the tonometer in the other and opposite direction. Cap **36** may, alternatively, be non-removable and made as an integral part of container **32**.

It will be further noted that the opposite ends **40** of shafts **31** are smooth and flat and are disposed perpendicularly to the axis of the said shafts. These flat, smooth ends **40** are adapted to be inserted at the appropriate times into staining cap **41** which is provided with a pad **42**. The pad **42** is impregnated with a suitable dyestuff or staining material of any known or desired nature, such as mild silver protein (N.F.), so that when the ends of the tonometer shaft are inserted into the staining cap **41** and into contact with pad **42**, the shaft ends **40** acquire a thin film of the dyestuff or staining material and thus, when the stained surfaces **40** are respectively placed in contact with the left and right eyes of a patient, patterns will be formed thereon responsive to the condition of each eye and the intra-ocular pressure thereof. FIGS. 7 and 8 indicate the opposing ends of the cyclinder with the letters L and R indicating left and right. These patterns thus formed are then transferred to a suitable strip of paper **43** which may be moistened with water or other suitable liquid and such an impression is shown at **44** in FIG. 12. In order to determine the significance of the impression and the particular pattern, the paper **43** with its impression **44** is placed beneath transparent scale **45** which is marked in terms of millimeters of mercury, thus making it possible to obtain a direct reading in terms of pressure from the impression made on the paper. The scale **45** illustrated is calibrated for use with a 5 gm. tonometer and similar scales can be calibrated for tonometers of 7.5 gm. and 10 gm.

From the foregoing description, taken in conjunction with the drawing, it will be understood that in using the tonometers of the present invention, each end surface **20** or **40** of the tonometer is brought into physical contact with pad **42** in staining cap **41** until the tonometer ends are provided with a suitable film or coating of staining material. Should the staining pad become unduly dry, it can be readily moistened. Then, as will be seen from FIG. 10, a stained end of the tonometer is gently contacted with the center of the cornea after having instilled a drop of topical anesthetic into the eye, and this procedure is carried out in such a manner that only the weight of the tonometer proper rests momentarily on the cornea and, depending upon the intra-ocular pressure, a distinctive pattern is formed on the stained tonometer end. The procedure is then repeated for the other eye of the patient but using the opposite end of the tonometer. The patterns formed on he tonometer ends are then impressed upon transfer paper **43** which has previously been moistened with water and any excess water removed as by blotting. As will be seen from FIG. 11 the transfer of the patterns to the transfer paper is made by holding the transfer paper between the thumb and forefinger in one hand and the tonometer end placed firmly against the paper for approximately two seconds, whereupon impression **44** as shown in FIG. 12 is formed on the transfer paper. In order to determine the significance and meaning of the impression **44** on paper **43** the paper is held under and in contact with the underside of the transparent scale **45** in such manner that the impression on the paper is located between the converging guide lines of the scale, and thereafter the scale is slid over the impression until

both guide lines are tangent to or very slightly overlapping the outer margins of the clear zone of the impression on the paper. It is then readily possible to read off the pressure from the scale in terms of millimeters of mercury. This pressure measurement indicates to the physician the state or condition of the eye which has thus been tested and informs the physician as to whether the tested eye is normal or abnormal insofar as intra-ocular pressure is concerned. It is further to be understood that ordinarily the patient will be retested from time to time and additional impressions obtained and filed so that comparisons can be made to determine progress or lack of progress of glaucoma and/or the effects of treatment for glaucoma or other eye abnormalities. It will be further understood that the principle of the invention is based on the flattening of a greater or lesser portion of the surface of the cornea depending on whether the intra-ocular pressure is lower or higher. This has been found to be an excellent measure of the existence of glaucoma or incipient glaucoma. It should be noted also that occasionally a pattern and the impression made therefrom is not substantially circular as it should be but may be somewhat oval or elliptical in shape, and when the impression is found to be of such character it should be discarded and a new test carried out. After both eyes have been tested in the manner described, the tonometer can be cleaned and sterilized with soap and water and the plunger can be boiled in order to insure sterility in case it is to be used again on the same or another patient. It is still further to be understood that the tonometers of both embodiments of the present invention are of exceedingly simple and inexpensive design and manufacture and can therefore be presented as a pre-sterilized disposable unit to ensure safety from infection and, if desired, because of their low cost, be discarded after use. It can be readily use even by those unskilled in eye tests and consequently the present tonometer is of special advantage and benefit in mass screening tests for glaucoma.

The container for the tonometer serves not only as a protective receptacle but also as a handle for manipulative purposes. It is, moreover, to be understood that the impressions or imprints made from the stained ends of the tonometer shaft surfaces can be retained to make a permanent record and/or can be placed on physicians' or clinics' office cards for filing and for ready reference. The collected impressions or imprints can thus also be employed for statistical purposes to report on eye conditions of specified population segments or groups classified according to geographic location, ethnic origin, cultural and dietary habits and the like.

What is claimed is:

1 A disposable tonometer comprising a hollow cylindrical combination container and handle assembly means to retain the tonometer within the cylinder, one end of said handle being provided with an inturned flange and the other end of which is provided with a pull-out ring, a tonometer proper within said container and handle comprising a cylindrical rod having a hub intermediate its ends, said hub being of a larger diameter than said inturned flange and pull-out ring whereby the tonometer is capable of axial movement within the combination container and handle during use and such movements are guided by said hub, and end means at each end of the tonometer by which intra-ocular pressure is indicated as a function of the area of eyeball engagement between the end means and the eyeball

2. A disposable tonometer in accordance with claim 1 in which said combination container and handle is composed of a transparent methyl methacrylate plastic and said rod, hub and pull-out ring are composed of an epoxy resin.

3. A disposable tonometer in accordance with claim 1 in which the inturned flange of the combination container and handle is provided with an interior bevelled surface which forms a stop, limiting movement of said rod when said hub abuts said surface and said pull-out ring having a similarly bevelled surface for limiting movement of said hub in the opposite direction, said inturned flange and pull-out ring providing central openings in alignment axially with said combination container and handle and through which openings the ends of said rod are adapted to project when said tonometer is in use for testing intra-ocular pressure of the eyes.

4. A disposable tonometer according to claim 1 in which the hub is provided with an annular groove, said combination container and handle provided with an opening in its wall in at least partial registry with the annular groove in said hub and a fastening member fitting into said opening and said hub groove to maintain said rod and hub substantially immobilized centrally within said combination container and handle and which fastening member is readily removable when the tonometer is to be used.

5. A disposable tonometer according to claim 1 in which the hub is provided with an annular groove, said combination container and handle provided with an opening in its wall in at least partial registry with the annular groove in said hub and means fitting into said wall opening and said hub groove to maintain said hub substantially immobilized within said combination container and handle and which means is readily removable when the tonometer is to be used and a membrane enclosing all of the members and enabling the thus enclosed tonometer, once sterilized, to be maintained in a sterile condition until used.

6. A disposable tonometer in accordance with claim 5 in which said means is a cylindrical pin with a reduced end dimensioned to pass through said wall opening and into said end of the groove until its larger end abuts said wall around the opening therein.

7. In combination, a tonometer composed of a relatively light dimensionally stable synthetic plastic material suitable for use in a hollow cylindrical container having axially aligned holes through one or both ends, and comprising a smooth centrally disposed cylindrical hub portion and axially aligned plunger shafts of lesser diameter extending in opposite directions from said hub portion, said plunger shafts being cylindrical in cross section and terminating in flat surfaces perpendicular to the longitudinal axis of the tonometer, end means on each of said shafts by which intra-ocular pressure is indicated as a function of the area of eyeball engagement between the end means and the eyeball, said hub portion and shafts being of fixed known weight, and a cylindrical container within which the tonometer is adapted to be received and within which it is longitudinally movable in opposite directions to expose the plunger shafts of the tonometer and said container being provided with limiting stop means at each end to prevent unintentional disassembly of the tonometer and its container while still permitting free longitudinal movement of said tonometer within said container.

8. A combination tonometer and container according to claim 7 in which one end of the container has an inwardly projecting lateral flange provided with a central opening which is larger than the diameter of the tonometer shaft but smaller in diameter than the said hub portion.

9. A combination tonometer and container according to claim 8 in which the opposite end of the container is provided with a snugly fitting externally applied cap having a laterally inwardly extending annular flange providing a central opening which is larger in diameter than the tonometer shaft but smaller in diameter than the said hub portion.

10. A combination tonometer and container according to claim 9 which further includes a staining cap provided with a staining pad, said staining cap being adapted to

be removably applied over each end of the tonometer shaft to form a film of staining material thereon.

11. A diagnostic method for determining the existence of glaucoma or incipient glaucoma in a human eye which comprises applying a film of staining material to each end surface of a tonometer comprising a smooth centrally disposed cylindrical hub portion and axially aligned plunger shafts of lesser diameter extending in opposite directions from the hub portion, said hub portion and shafts being of fixed known weight, bringing each of the stained tonometer end surfaces into contact with the cornea of the eye of a patient in such manner that only the weight of the tonometer itself rests momentarily on the cornea, transferring the patterns so formed on the tonometer end surfaces to transfer paper to form a visible record and then measuring the characteristics of each

such impression with reference to a scale from which can be determined the intraocular pressure of the tested eyes.

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